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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,739	03/14/2002	Masayuki Amagai	201487/1070	5390

7590 03/24/2004

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EXAMINER

LI, QIAN JANICE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

2874  
**Advisory Action**

Application No.

09/937,739

Applicant(s)

AMAGAI ET AL.

Examiner

Q. Janice Li

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☒ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

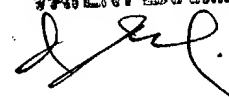
Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 2-8, 10-16, 18-23, 25.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

JANICE LI  
PATENT EXAMINER



Continuation of 5. does NOT place the application in condition for allowance because: Even though the amended claims limit the recipient to rodent, making the knockout donor animal is still unpredictable.

In the response after final, applicants first appear to suggest that the knockout donors do not need to have a phenotype or can be easily identified with methods well known in the art. The arguments are not persuasive because in this case the phenotype means obtaining a donor rodent animal truly lacking the gene encoding the autoantigen, mature, and viable, which are basic requirements for practice the invention. Peterson article is replete with difficulties in making a desired knockout mouse and thus supports the enablement rejection. The Office is not aware of, and the specification fails to teach any animal that is naturally lacking a gene encoding an auto-antigen protein, which could be identified using conventional methods.

Applicants then argue that Logan reference deals with transgene expression whereas making a knockout animal is more straightforward. In response, making a knockout animal also requires a transgene construct to disrupt the endogenous gene, thus, will encounter similar issues of making and expressing a proper genetic construct.

Applicants presented table 1 listing 11 new references to address issues associated with selection of autoantigen. The new references will not be considered since they are not directed solely to issues newly raised in the final rejection.

Applicants cited case law to argue that the presence of inoperative embodiments within the scope of a claim does not necessarily render that claim not enabled. In response, it is noted that in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In re Soll, 97 F.2d 623, 38 USPQ 189 (CCPA 1938).

With respect to the adoptive transfer models, even though a few of them are well known in the art, it has been established that genetic factors also play a role in these models. Undue experimentation is necessary to define the numerous models encompassed. The newly cited exhibits have not been considered since they are not directed solely to issues newly raised in the final rejection..